

Notice of Allowability

Application No.

09/863,803

Examiner

Q. Janice Li, M.D.

Applicant(s)

RADE ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 5/7/07.
2. ☒ The allowed claim(s) is/are 29,30,33-49,52-58,68 and 69.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


Q. JANICE LI, M.D.
PRIMARY EXAMINER

NOTICE OF ALLOWANCE

This action is in response to the amendment filed May 7, 2007. Claims 31, 32, 50, 51, 59-67, 70-72 have been cancelled. Claims 29, 30, 33, 34, 52, 56 have been amended. Claims 29, 30, 33-49, 52-58, 68, 69 are pending. All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office action mailed on 3/6/07 are withdrawn in view of the amendments.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Stephana E. Patton on May 15, 2007.

An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment that places this application in condition for allowance. During the telephone conversation, the applicant representative requested an extension of time for one MONTH(S) and authorized the Commissioner to charge Deposit Account No. 04-1105 for the required fee for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an

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amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The claims have been amended as follows:

Claim 29. (currently amended) A method for treating a mammal to resist early vein graft failure comprising,

a) introducing into endothelial cells of an autologous vein graft from the mammal an effective amount of at least one nucleic acid encoding one of the following agents: thrombomodulin (TM), NF- κ B inhibitor, or a functional fragment of the TM; provided that when the agent is thrombomodulin, the nucleic acid further encodes the NF- κ B inhibitor, wherein the introducing is performed *ex vivo* or by direct injection into the graft, and

b) transplanting the vein graft into the mammal when the introducing is performed *ex vivo*.

Claim 30. (currently amended) A method for engineering a vein graft of a mammal to resist early graft failure, the method comprising:

a) introducing into endothelial cells of an autologous vein graft from the mammal an effective amount of at least one nucleic acid encoding one of the following agents: thrombomodulin (TM), NF- κ B inhibitor, or a functional fragment of the TM; provided that when the agent is thrombomodulin, the nucleic acid further encodes the NF- κ B inhibitor, wherein the introducing is performed *ex vivo* or by direct injection into the graft, and

b) transplanting the vein graft into the mammal when the introducing is performed *ex vivo*.

In claim 46, the letter -- b -- was inserted in place of "~~cb~~".

Claim 52. (currently amended) A method for treating a mammal to resist early vein graft failure comprising,

- a) introducing into endothelial cells of an autologous vein graft from the mammal an effective amount of at least one nucleic acid encoding at least one of the following agents: thrombomodulin (TM), NF- κ B inhibitor, or a functional fragment of the TM; provided that when the agent is thrombomodulin, the nucleic acid further encodes the NF- κ B inhibitor, wherein the introducing is performed *ex vivo* or by direct injection into the graft, the nucleic acid being expressed from a recombinant adenovirus vector comprising a first adenovirus inverted terminal repeat (ITR) operably linked to the nucleic acid, and
- b) transplanting the vein graft into the mammal when the introducing is performed *ex vivo*.

Claim 56 (currently amended) A method for treating a mammal to resist early vein graft failure comprising,

- a) introducing into endothelial cells of an autologous vein graft from the mammal an effective amount of at least one nucleic acid encoding at least one of the following agents: thrombomodulin (TM), NF- κ B inhibitor, or a functional fragment of the TM; provided that when the agent is thrombomodulin, the nucleic acid further encodes the NF- κ B inhibitor, wherein the introducing is performed *ex vivo* or by direct injection into the graft, the nucleic acid being expressed from a recombinant adeno-associated virus (AAV) vector ~~comprising~~ and operably linked to an adeno-associated virus inverted terminal repeat (ITR) ~~and the nucleic acid~~, and
- b) transplanting the vein graft into the mammal when the introducing is performed *ex vivo*.

Conclusion

Claims 29, 30, 33-49, 52-58, 68, 69 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730.

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The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on 571-272-0739. The fax numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

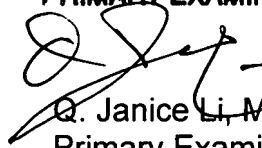
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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

**Q. JANICE LI, M.D.
PRIMARY EXAMINER**



Q. Janice Li, M.D.
Primary Examiner
Art Unit 1633

QJL
May 15, 2007